REMARKS/ARGUMENTS

Applicants acknowledge with appreciation the statements in the Office Action (page 5, #2) that the former rejections under 35 U.S.C. §102(a) and (b) and under 35 U.S.C. §112, first paragraph were overcome due to Applicant's arguments and amendments and the declaration filed in the case.

Claims 1-9 are pending in the application. Claim 4 was made redundant due to amendments to claim 1 and therefore has been canceled. Claims 5 and 6 have also been canceled solely in order to advance prosecution. Claim 1 has been amended to clarify the scope of the invention as further discussed below. No new matter has been added by way of amendment. Reexamination and reconsideration of the claims are respectfully requested.

The Rejection of Claims Under 35 U.S.C. §112, Second Paragraph, Should Be Withdrawn

The Office Action (page 2, #2) rejected claims 1-9 under 35 U.S.C. §112, second paragraph, as being indefinite "because it is unclear what is meant by the new limitation 'a particular mouse strain and identifying whether said strain is a low nitric oxide (NO) responder strain or a high NO responder strain.'"

As discussed in the specification (for example, in the paragraph spanning pages 7 and 8, on page 8 (last paragraph), and page 9 (first paragraph)), there are a number of different ways in which one of skill in the art can determine whether a particular mouse strain is a low NO responder strain or a high NO responder strain. Particularly, as discussed in the last paragraph on page 8, the innate inflammatory responses of macrophages of many important mouse strains are known in the art. Accordingly, Applicants believe that the meaning of the limitation was clear. However, solely in order to advance prosecution, independent claim 1 (and therefore also claims 2-9, which are dependent on or incorporate the limitations of claim 1) has been amended in accordance with the suggestion in the Office Action to clarify that a strain is identified as a low NO responder strain or a high NO responder strain when said strain is exposed to bacterial antigens. Support for the amendment can be found throughout the specification, including the passages cited above in this paragraph, and therefore no new matter has been added.

In view of this clarification, Applicant respectfully submits that the rejection of claims 1-9 on this basis should be withdrawn.

The Office Action (page 3, first full paragraph) rejected claim 1 under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential steps due to their recitation of the phrase "if appropriate."

As discussed in the specification (for example, page 13 (paragraph at top of page)) and as illustrated in Example 2 (pp. 29 *et seq.*, particularly p. 31, last paragraph) and claim 4 (now canceled), the amount of arginine in the diet can be adjusted to enable a maximal immune response. In order to advance prosecution, independent claim 1 (and therefore also claims 2-9, which are dependent on or incorporate the limitations of claim 1) has been amended in accordance with the suggestion in the Office Action to clarify that if said mouse strain is a low nitric oxide responder, a feeding regimen can be rationally selected that has high levels of arginine and if said mouse strain is a high nitric oxide responder, a feeding regimen can be rationally selected that has low levels of arginine.

Similarly, as discussed in the specification (for example, in the last paragraph on p. 25 and the first paragraph on p. 26 as well as in working Example 1 and Figure 3), inhibitors of NOS2 can be used to modulate the immune response. Therefore, claim 1 has also been modified to specify that if said mouse strain is a high nitric oxide responder, said test mouse can be treated with an inhibitor of nitric oxide synthase-2. However, Applicant notes that in some instances, it may not be necessary to both modify the mouse diet and to treat the mice with a NOS2 inhibitor in order to obtain a mouse model of the invention, as one of skill in the art would readily appreciate. Accordingly, claim 1 has been amended to clarify this point.

Support for these amendments can be found throughout the specification, including the passages cited above, and therefore no new matter has been added. In view of these clarifications, Applicant respectfully submits that the rejection of claim 1 on these bases should be withdrawn.

The Office Action (page 3, last paragraph) states that claim 1 is vague and indefinite "because part (B) recited 'selecting a dose of *Chlamydia* to be administered to a test mouse of said strain' and part (e) recites 'administering *Chlamydia* to said test mouse' making it unclear whether the *Chlamydia* is actually administered in part (b) or just 'selected' and it is also unclear whether these are the same *Chlamydia*."

In order to advance prosecution, part (d) (formerly part (e)) of independent claim 1 (and therefore also claims 2-9, which are dependent on or incorporate the limitations of claim 1) has been amended to specify that "said dose" is administered to said test mouse. This amendment should clarify that the dose of *Chlamydia* selected in step (b) is administered to the test mouse in step (d).

In view of this clarification, Applicant respectfully submits that any rejection of claim 1 on this basis should be withdrawn.

The Office Action (page 4, first full paragraph) states that part (f) of claim 1 (which is now part (e) of claim 1) is vague and indefinite "because the specification teaches that when a prophylactic treatment is used the prophylactic has to be administered prior to the administration of the *Chlamydia*. Instant claim 1 has the prophylactic being administered after the *Chlamydia*. It is unclear how this would work."

As discussed in the specification (for example, in the paragraph spanning p. 13 to p. 14), the order of steps in the method may vary depending on the treatment being evaluated. Thus, if the treatment is prophylactic, the treatment will typically be administered to the mouse prior to the administration of the test inoculation or dose of *Chlamydia*. Similarly, if the treatment is therapeutic, the treatment will typically be administered to the mouse after administration of the test inoculation of *Chlamydia*. Moreover, the order of the steps of selecting a mouse strain, selecting a dose of *Chlamydia*, and selecting a feeding regimen is not important so long as the object of the invention is accomplished; that is, so long as the method permits evaluation of the efficacy of a therapeutic or prophylactic treatment of *Chlamydia*-induced disease.

In view of this clarification, Applicant respectfully submits that any rejection of claim 1 on this basis should be withdrawn.

The Office Action (page 4, second full paragraph) states that "[t]he last three lines of claim 1 are vague and indefinite because it recites that the reference mouse did not receive prophylactic or therapeutic treatment yet it is unclear whether the reference mouse received the same feeding regimen and is the same strain of mouse as the test mouse."

As discussed in the specification (for example, p. 7, first full paragraph), the test mouse and the reference mouse may differ in multiple ways, and one of skill will be able to design and use a mouse model of the present invention that permits evaluation of the consequences of various differences in genetics, treatment, *etc.* on *Chlamydia*-induced disease. However, in order to advance prosecution and clarify the scope of claim1, the last three lines of claim 1 have been deleted.

In view of this clarification, Applicant respectfully submits that any rejection of claim 1 on this basis should be withdrawn.

The Office Action (page 4, last paragraph) states that claim 5 is vague and indefinite and also states (page 5, first full paragraph) that claim 6 should add a correlation step.

In view of the clarification discussed above that one of skill will be able to design and use a mouse model of the present invention, Applicant believes that one of skill will similarly be able to determine when particular steps and treatments are appropriate and when they are not. However, in order to advance prosecution, because this subject matter is encompassed within the scope of claim 1, claims 5 and 6 have been cancelled.

In view of these amendments, Applicant respectfully submits that any rejection of the claims on these bases should be withdrawn.

CONCLUSION

In view of the above amendments and remarks, Applicant submits that the rejections of the claims under 35 U.S.C. §§112, second paragraph, are overcome. Applicant respectfully

submits that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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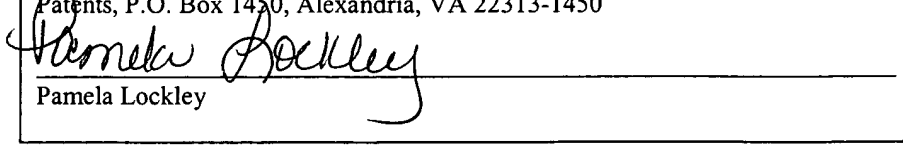

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